

NOV 22 2000

K001563

V. 510(k) SUMMARY

Submitted by: Scion Cardiovascular, Inc.
14256 SW 119 Avenue
Miami, FL 33186
Phone: (305) 263-8199
Fax: (305) 263-8189

Contact Person: David B. Jones

Date Prepared: November 16, 2000

Proprietary Name: Scion Cardiovascular SciPro™

Common Name: Flexible Stone Dislodger and Retrieval Set

Classification: Class II: 21 CFR §: 876.4680 and 878.4200

Classification Name: Ureteral Stone Dislodger (FGO) and Retrieval Set (DRE)

Predicate Device:

Boston Scientific:	K970121	Stone Dislodger Basket
Boston Scientific:	K963750	Retrieval Snare
Boston Scientific:	K951309	Stone Dislodger Flexible
MED Institute:	K914555	Byrd Workstation (BW)

Device Description: The Scion Cardiovascular SciPro™ is a guide wire based retrieval device. Models come in multiple configurations based on length, diameter and basket size. The proximal body has 0.014-0.035" diameters and 150 - 300cm lengths, and the baskets are 4-7mm. The 0.014" and 0.018" proximal bodies are hypo tubing and the 0.035" proximal body is PEEK. The core inner wire is 304 stainless steel and the baskets are nitinol. The SciPro™ is visible under fluoroscopy and has a radiopaque platinum/tungsten distal soft floppy tip. When wire is pulled/pushed the wire/basket is deployed/retracted. Rotating the proximal sleeve counter-clockwise one-quarter (1/4) turn and pushing the core wire secures the object by closing the wires/basket. A polyurethane membrane is available on the distal half of the basket models to capture very small fragments. The molded polyurethane membrane has 200-350 micron holes.

Intended Use: The Scion Cardiovascular SciPro™ is intended for use during urological and/or gastroenterological procedures requiring the removal of calculi, debris and/or fragment retrieval of catheter tubing, wire guides, pull wires and plastic stents, and other foreign objects.

Technological

Characteristics: The Scion Cardiovascular SciPro™ technological characteristics are the same as the Boston Scientific and MED Institute predicate devices. The Scion Cardiovascular SciPro™ works in the same manner as the approved predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 2001

Mr. David B. Jones
Consultant and Vice President of RA & QA
Scion Cardiovascular, Inc.
14256 SW 119 Avenue
MIAMI FL 33186

Re: K001563
Trade/Device Name: SciPro™ Flexible Stone Dislodger and Retrieval Set
Regulation Number: 21 CFR §876.4680
Regulation Name: Ureteral stone dislodger
Regulatory Class: II
Product Code: 78 FGO
Dated: August 17, 2000
Received: August 24, 2000

Dear Mr. Jones:

This letter corrects our substantially equivalent letter of November 22, 2000, regarding the SciPro™ Flexible Stone Dislodger and Retrieval Set from Scion Cardiovascular, Inc., which listed an incorrect product code.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

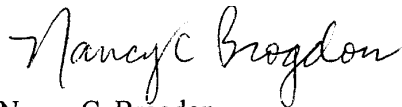
Page 2 Mr. David Jones

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001563

IV. Statement of Indications for Use

Applicant: Scion Cardiovascular, Inc.
14256 SW 119 Avenue
Miami, FL 33186
Phone: (305) 263-8199
Fax: (305) 263-8189

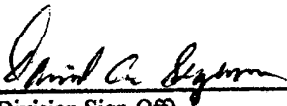
510(k) Number: K001563

Device Name: SciPro™

Indications For Use: The Scion Cardiovascular SciPro™ is intended for use during urological and/or gastroenterological procedures requiring the removal of calculi, debris and/or fragment retrieval of catheter tubing, wire guides, pull wires and plastic stents, and other foreign objects.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001563

Prescription Use ☒

or Over-the-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Confidential

Device ?

11/16/00